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REMARKS

This Amendment is responsive to the Final Office Action dated January 17, 2007. Claims 1 and 6 have been amended. Claims 28-42 and 44-68, which were previously withdrawn, have now been cancelled. New claims numbered 69-71 have been added. Claims 1-15, 17-27 and 69-71 are pending, with claims 7, 10 and 13 withdrawn due to restriction.

Applicant respectfully requests entry of the after-final claim amendments and additions. The amendments are minor in that they either correct grammatical errors or merely provide greater clarity. The new claims recite limitations found in the claims as previously presented. Accordingly, Applicant respectfully submits the amended and new claims raise no new issues, and required no further search. Further, Applicant respectfully submits that the amended and new claims are in condition for allowance, or at least are in better form for appeal relative to the claims as previously presented.

Claim Objections

The Final Office Action objected to claims 44-47 because they depended upon cancelled claim 43. Applicant has cancelled claims 44-47, which were previously withdrawn due to restriction, without prejudice or disclaimer. Accordingly, this objection is moot.

Claim Rejection Under 35 U.S.C. § 102(e)

The Final Office Action rejected claims 1-6, 8, 9, 11, 12, 14, 15 and 17-27 under 35 U.S.C. § 102(e) as being anticipated by Ni et al. (US 2004/0111041, herein referred to as Ni). Applicant respectfully traverses the rejection. Ni fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Ni fails to disclose or suggest determining when a patient is attempting to sleep, as recited by independent claim 1. Instead, Ni describes detecting when a patient is sleeping by detecting sleep onset and termination. The system described by Ni compares a sleep-related signal to a threshold value and detects sleep based on the comparison. Ni does not disclose or suggest determining when a patient is attempting to sleep. As one example, the

system of Ni does not disclose or suggest detecting when a patient is awake but attempting to sleep. Ni is limited to determining whether a patient is sleeping.

Furthermore, Ni fails to disclose or suggest determining a value of at least one activity metric based on activity levels determined when the patient is not attempting to sleep, as recited by independent claim 1 as amended. As discussed above, Ni does not determine when a patient is attempting to sleep. Moreover, contrary to the requirements of amended claim 1, Ni is focused on monitoring activity to determine when the patient falls asleep and wakes up. In other words, the Ni system looks at activity when the patient is not asleep to determine when the patient falls asleep. Merely looking at activity to determine when the patient falls asleep is clearly not the same as determining an activity metric value based on activity levels when the patient is not attempting to sleep. This teaching of Ni would not have even suggested determining the value of at least one activity metric based on activity levels determined when the patient is not attempting to sleep.

As another example, with respect to claim 11, Ni fails to disclose or suggest that the sleep quality metric comprises sleep latency, and determining values of the sleep quality metric comprises identifying a first time when the patient is attempting to fall asleep, identifying a second time when the patient falls asleep based on at least one of the physiological parameters, and determining an amount of time between the first and second times. Ni does not disclose or suggest identifying a first time when the patient is attempting to fall asleep. Ni merely describes identifying when the patient falls asleep. For at least these reasons, Ni clearly fails to disclose or suggest determining an amount of time between a first time when the patient is attempting to fall asleep and a second time when the patient falls asleep.

As another example, Ni fails to disclose or suggest selecting an activity metric value from a plurality of predetermined possible values, as recited in claim 18. Paragraphs [0070] and [0075] of Ni discuss a moving average of activity, and comparison to the threshold value, but do not in any way suggest selection of an activity metric value from a plurality of predetermined possible values.

Further, with respect to claim 19, Ni does not disclose or suggest determine a percentage of time that activity levels were above or threshold, or determining a percentage of time that activity levels were below a threshold. Paragraphs [0055] and [0056] of Ni do teach comparison

to a threshold to determine amounts of time sleeping, but do not suggest determining a percentage of time above or below a threshold.

Also, with respect to Applicant's claim 22, Ni fails to disclose or suggest associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set, for each of the plurality of therapy parameter sets, determining a representative value of each of the at least one sleep quality metric based on the sleep quality metric values associated with the therapy parameter set, and for each of the plurality of therapy parameter sets, determining at least one activity metric value based on the activity levels associated with the therapy parameter set.

Ni does not disclose or suggest associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set. Ni merely describes determining therapy parameters based on whether or not the patient is sleeping. As one example, Ni describes adjusting a lower rate limit of a pacemaker based on recognition of sleep or non-sleep states.[1] In contrast, Applicant's claim 22 requires that, when a sleep quality metric value or an activity level is determined, the therapy parameter set that was currently used to deliver stimulation is associated with the sleep quality metric value or activity level. In this manner, sleep quality and activity metrics may be used to, evaluate the effectiveness of the therapy parameters in some embodiments according to the claim.[2]

Further, with respect to claim 23, Ni does not disclose or suggest a list of therapy parameter sets with associated sleep and activity metrics. As discussed above, Ni does not suggest association of determined sleep and activity metrics with the therapy parameter set active when the metric was determined, e.g., for the purpose of evaluating the therapy parameter sets. Additionally, although paragraphs [0053]-[0056] mention historical sleep information and programming commands, they do not in any way describe or imply a list of therapy parameter sets. The mere mention of programming commands and historical sleep information does not suggest a list of therapy parameter sets with associated sleep and activity metrics.

Moreover, Ni does not in any way suggest ordering a list of therapy parameter sets, as recited in claim 24. The Final Office Action did not discuss claim 24, or in any way explain how

[1] Ni, paragraph [0026].
[2] *See* Summary of Invention of present application.

Ni could be considered applicable to its requirements. **Applicant respectfully suggests that the rejection of claim 24 must be withdrawn or explained in any subsequent Office Action.** In other words, Applicant respectfully suggests that an Advisory Action should not be issued without a withdrawal or explanation of the rejection of claim 24.

Ni also fails to disclose or suggest a medical device comprising at least one of a trial neurostimulator and a trial pump, as recited by claim 27. Ni makes no mention of a trial neurostimulator or a trial pump. Instead, Ni describes implementing sleep detection methods within a cardiac rhythm management system or hypoglossal nerve stimulator.[3] Ni does not disclose or suggest a trial neurostimulator or a trial pump.

In order to support an anticipation rejection under 35 U.S.C. § 102(e), it is well established that a prior art reference must disclose each and every element of a claim. This well known rule of law is commonly referred to as the "all-elements rule."[4] If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. § 102(e) is improper.[5]

Ni fails to disclose each and every limitation set forth in independent claim 1. Claims 2-6, 8, 9, 11, 12, 14, 15 and 17-27 are dependent upon claim 1 and are also in condition for allowance. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 1-6, 8, 9, 11, 12, 14, 15 and 17-27 under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

New Claims

Applicant has added new claims 69-71 to the present application. Ni does not disclose or suggest the requirements of the new claims. For example, as discussed above with respect to claim 22, Ni does not disclose or suggest associating each of the determined sleep quality metric values and each of the activity levels determined when the patient is not attempting to sleep with a current therapy parameter set, for each of the plurality of therapy parameter sets, determining a

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[3] Ni, paragraph [0033].
[4] *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").
[5] *Id. See also Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225 (CAFC 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).

representative value of each of the at least one sleep quality metric based on the sleep quality metric values associated with the therapy parameter set; and for each of the plurality of therapy parameter sets, determining at least one activity metric value based on the activity levels associated with the therapy parameter set, as required by new independent claim 69. No new matter is added by claim 69.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 3-19-07

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